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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,734	09/11/2000	Winfried Edelmann	AHN-001DV1	9039
959	7590	05/03/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			DAVIS, RUTH A	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/658,734	EDELMANN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ruth A. Davis	1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 1-27-04.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13,24 and 29-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13,24,29-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1-2003</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's Request for Continued Examination and amendment filed January 27, 2004 has been received and entered into the case. Claims 14, 23 and 25 – 28 are canceled; claims 33 – 71 are added; claims 13, 24, and 29 – 71 are pending and have been considered on the merits. All arguments have been fully considered.

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 34 – 37, 44 – 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34, 35 and their dependents are drawn to a method of identifying compounds, however are rendered vague and indefinite for reciting "capable of" because it is unclear if the compounds must prevent fertilization or merely may potentially prevent fertilization. Moreover, it is unclear how one would identify a compound that might have a desired activity.

Claims 34 – 37 and their dependents are drawn to methods for identifying compounds, however are rendered vague and indefinite for reciting "assaying for modulation" because it is unclear if candidate compounds that inhibit or stimulate expression of MSH5 are being assayed, or if the expression of MSH2 is being assayed.

*Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 13, 24, and 29 – 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fishel in view of Hollingsworth (Genes & Development, 1995).

Applicant claims methods for identifying compounds useful as a contraceptive, for inhibiting meiosis, preventing fertilization, inhibiting and stimulating chromosome synapsis. The methods comprise contacting MSH5 or a cell expressing MSH5 with the compound, determining activity or expression of MSH5 in the presence of the compound, selecting a compound that inhibits MSH5, and identifying the compound useful for a contraceptive,

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inhibiting meiosis, preventing fertilization and inhibiting chromosome synapsis (or stimulating MSH5 for stimulating chromosome synapsis). The compound may be an antisense MSH5 nucleic acid, inhibitor of MSH5 substrate activity, a small molecule, MSH5 antibody, peptide or peptidomimetic.

Fishel teaches a method for determining if a composition (test compound) affects (or modulates) expression of a gene encoding a MutS homolog (MSH) (col.9 line 10-15) wherein the MutS homolog is MSH5 (col.4 line 35-40). The method comprises administering the test composition (or compound) to a cell containing the MutS homolog (or MSH5) and determining the activity or expression of the MutS homolog to determine if the compound effects (or modulates) MutS homolog activity (col.9 line 29-45).

Fishel does not teach the method wherein the compound is useful to inhibit meiosis, prevent fertilization, as a contraceptive, or to inhibit/stimulate chromosome synapsis. However, Hollingsworth teaches that MSH5 is a meiosis specific gene, active to facilitate meiosis and meiotic chromosome synapsis (abstract) in bacteria, yeast and humans (p.1729). Hollingsworth additionally teaches that mutant MSH5 (or inhibited activity thereof) results in decreased spore (or gamete) viability (p.1735, 1736). Moreover, Hollingsworth suggests that inhibited or reduced activity of MSH5 inhibits meiosis, chromosome synapsis and decreases fertility. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use inhibitors of MSH5 activity identified by the methods of Fishel, as inhibitors of meiosis, chromosome synapsis and fertility, since the gene was known to facilitate these activities. It would have been further obvious to one of ordinary skill in the art to identify the inhibitors useful for contraceptive agents, since it was well known in the art that meiosis, chromosome

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synapsis and fertility are required for conception. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the teachings of Hollingsworth to use the identified compounds of Fishel, as inhibitors of meiosis, fertilization and chromosome synapsis, as well as contraceptive agents.

Fishel does not teach the method wherein the compound may be any of the claimed types of compounds. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use any compound in the method of Fishel, since the method is directed to determining the effects of compounds (any compound) on MSH5. It would have been well within the purview of one of ordinary skill in the art to use any compound in the method, since the method is specifically directed to testing compounds for their effect on MSH5. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to use any type of compound in the methods of Fischel with a reasonable expectation for successfully determining the effect of a compounds on MSH5.

### ***Response to Arguments***

Applicant argues that the references do not teach the relationship between MSH5 and meiosis or contraception; and has submitted affidavits stating that the invention was conceived prior to October 1, 1998.

However, these arguments fail to persuade because Hollingsworth (1995) specifically teaches a direct relationship of MSH5 to meiosis and chromosome synapsis in yeast, bacteria and

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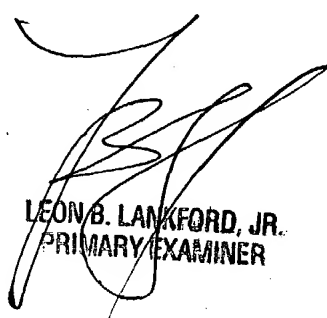
humans (prior to October 1, 1998). In addition, it is noted that the affidavits filed on January 27, 2004 under 37 CFR 1.131 are not signed, and are therefore defective.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis; rad  
April 28, 2004.



LEON B. LANKFORD, JR.  
PRIMARY EXAMINER